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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,918	09/29/2006	Yoshinori Abe	4633-0189PUS1	5532

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EXAMINER	
GUGLIOTTA, NICOLE T	
ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
04/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,918	ABE ET AL.	
	Examiner	Art Unit	
	NICOLE T. GUGLIOTTA	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2 - 10 & 12 - 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 - 10 & 12 - 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/17/2007, 9/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). However, applicant has failed to claim foreign priority in the first sentence of the specification or in the application data sheet (ADS). Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and § 1.55(a). See MPEP § 601.05 [R-5] & 37 CFR 1.76 (b)(6). Correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 2, 3, 6 - 8, and 12 - 15 rejected under 35 U.S.C. 102(b) as being anticipated by Steffen et al. (*Surf. Interface Anal.* **29**, 386 – 391 (2000); submitted by applicant).

4. In regard to claims 2 and 6, Steffen et al. disclose a diamond-like carbon (DLC) film system that consists of a chemically inert, uniform, dense and highly tetrahedrally bonded, hydrogenated amorphous carbon film (ta-C:H) with high adherence to the

substrate and bioactive heparin macromolecules that are covalently bonded to the ta-C:H film surface (Figure 1 & Page 387, 2nd Col., 2nd paragraph).

5. In regard to claims 3 and 4, Examiner interprets these as product-by-process claims. Therefore these claims are not dependent upon the process of graft polymerization. Graft polymerization will not result in a different structure than suggested by the prior art discussed below (see paragraphs 15 and 16 of this office action).

6. Examiner refers applicant to MPEP § 2113 [R - 1] regarding product-by-process claims. "The patentability of a product does not depend on its method or production. If the product in the product-by-process claim is the same as or obvious from a product or the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777, F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citation omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218, USPQ 289, 292 (Fed. Cir. 1983)

7. In regard to claim 3, Steffen et al. disclose heparin to be a polymer, where n – 7 – 10 (Figure 1). Schwarz et al. disclose grafting processes can be used to coat or modify the surface of the medical device or a part of the medical device with the following materials: fluorine-based monomers (hydrofluorocarbons), one or more

monomers used alone or in combination in order to form blends, cross-linked polymers, copolymers and interpenetrating network of polymers (Column 11, Lines 3 – 15).

8. In regard to claim 7, Steffen et al. disclose "Hollohan" discloses results of plasma treatment *promoted ionic heparin binding* between its negatively charged sulphate ester groups and the quaternary ammonium sites of the alkylated samples (Page 388, Col. 2, second paragraph of results and discussion section).

9. In regard to claim 8, Steffen et al. disclose the bioactive heparin macromolecules (Figure 1) to have a carboxyl group (COO^-), an amido group (-NH-), and a hydroxy group (-OH). In addition to an amine group ($-NH_2$) bonded to the DLC film surface.

10. In regard to claim 12, Steffen et al. disclose the substrate materials (base materials) were PTFE vascular prostheses, PTFE and polystyrene films, as well as Si(100) wafers (Page 388, Col. 1, first paragraph of the experimental section).

11. In regard to claims 13, 14, and 15, Steffen et al. disclose the film and surface-immobilized bioactive molecules to optimize haemocompatibility for artificial implants of the cardiovascular system (Abstract and Page 386, Col.1, paragraph 1). In addition, the use of DLC films on polymers give rise to a universal application of these carbon materials for medical devices, such as total joint replacements, heart valves, catheters, stents, intravascular insertion devices and more (Page 388, Col. 1, first paragraph).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 3 – 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al., in view of Palmaz et al. (U.S. Patent No. 6,537,310 B1)

14. Steffen et al. disclose a biocompatible layer (heparin) attached to a diamond-like carbon (DLC) layer, which is applied to a substrate (base material). However, Steffen et al. do not disclose the biocompatible layer to contain silicon of vinylmonomers containing fluorine.

15. Palmaz et al. disclose the numerous attempts to increase endothelialization of implanted stents, including imparting a diamond-like carbon coating onto the stent (U.S. Pat. No. 5,725,573), coating the stent, under ultrasonic conditions, with a synthetic or biological, active or inactive agent, such as heparin, endothelium derived growth factor, vascular growth factors, *silicone*, polyurethane, or *polytetrafluoroethylene* (U.S. Pat. No. 5,891,507), coating a stent with a silane compound with vinyl functionality, then forming a graft polymer by polymerization with the vinyl groups of the silane compound (U.S. Patent No. 5,782,908), *grafting monomers, oligomers or polymers onto the surface of*

the stent using infrared radiation, microwave radiation or high voltage polymerization to impart the property of the monomer, oligomer or polymer to the stent (U.S. Pat. No. 5,932,299).

16. It would have been obvious to one skilled in the art at the time the invention was made to graft biocompatible layers containing silicon and/or a vinylfluoride monomer molecules (such as silicon and polytetrafluoroethylene) because such components and methods are commonly found in the art for increasing endothelialization and antithrombogenicity, as taught by Palmaz et al. This is further supported by Kiezulas (U.S. Patent No. 5,026,607), Schwarz et al. (U.S. Patent No. 6,368,658 B1), Sasaki et al. (U.S. Patent No. 5,489,303), David (U.S. Patent No. 6,197,120 B1), Bray et al. (U.S. Patent No. 6,468,642 B1) and Veerasamy et al. (US 2001/0044030 A1).

17. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al., in view of Lemelson et al. (U.S. Patent No. 6,083,570).

18. Steffen et al. disclose a biocompatible layer attached to a diamond-like carbon (DLC) layer, which is applied to a substrate (base material). However, Steffen et al. do not disclose the use of an intermediate film between the DLC and the substrate (base material).

19. Lemelson et al. disclose articles with synthetic diamond or diamond-like carbon coatings with an intermediate amorphous metal bonding later. The residual stress in diamond and diamond-like thin film coatings applied to metal, cermet and ceramic

substrates can be reduced to acceptably low levels by using an intermediate film coating of amorphous ("glassy") metal (Column 3, Lines 54 - 65). Such articles include dental tools and medical prostheses or implants intended for long-term use inside the human body (Column 4, Lines 4 – 11). The intermediate layer may be comprised of carbides or silicon. SiC is most preferred (Column 4, Lines 33 - 38).

20. It would have been obvious to one skilled in the art of diamond-like carbon films at the time the invention that the addition of an intermediate SiC layer between the DLC would help to reduce the residual stress in diamond-like carbon thin film coatings used for medical applications. An organosilicon intermediate layer for increased adherence between a substrate and a DLC is also disclosed by Kato et al. (U.S. 5,763,072).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE T. GUGLIOTTA whose telephone number is (571)270-1552. The examiner can normally be reached on M - Th 8:30 - 6 p.m., & every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NICOLE T. GUGLIOTTA
Examiner
Art Unit 1794

/Carol Chaney/

Supervisory Patent Examiner, Art Unit 1794